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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,754	02/13/2002	Daniel L. Marks	96,886-L	1079

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EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,754	MARKS ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 7-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/3/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II, claims 5 and 6 in the reply filed on 10/17/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, And/Or Claims

Claims 1-15 are pending. Claims 1-4 and 7-15 are withdrawn from further consideration as being drawn to a nonelected Invention.

Claims 5 and 6 are under examination.

Information Disclosure Statement

The information disclosure statement filed 5/3/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The crossed references were are not available to the examiner at the time of examination.

Applicants may, in response to this and no later Office Action, submit the missing references. Such submissions will be considered to have been part of the respective Information Disclosure Statement filed on 5/3/2004, and the PTO-1449 will be updated accordingly. No fee for the submission of such references

is required, nor should applicants file an additional form PTO-1449 with the missing references.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are drawn to a method of preventing or treating a pathological feeding behavior, cachexia in an animal comprising administering an effective amount of a mammalian melanocortin 4 (MC-4) receptor antagonist to the animal. The claims do not require that a receptor antagonist possesses any particular structural characteristic, or distinguished structural modification. As such an inhibitor of MC-4 R that ameliorates or inhibits cachexia comprises any compound, peptide, antibodies or combination of all. Therefore, the claims are drawn to a genus of a genus of receptor antagonist.

Factors to be considered when determining whether there is sufficient evidence of possession include the level of skill and knowledge of the art, partial structure, physical and/or chemical properties, functional characteristics, alone or coupled with a known or disclosed correlation between structure and function,

and method of making the chemical invention (Written description guidelines, Federal Register, vol. 66, no. 4, January 2002, p 1106, column 2).

There are no particular structures identified as being associated with a MC-4 receptor antagonist. Thus the essential characteristics of a receptor antagonist are not disclosed, and the artisan would not conclude that Applicant was in possession of this genus as broadly claimed.

This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written descriptioninquiry, is *whatever is now claimed* (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (see Vas-Cath at page 1116).

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed.

Cir. 1997). In Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B (1), the court states an adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.

As discussed above, the skilled artisan cannot envision the detailed amino acid sequence or chemical structure of the encompassed genus of receptor antagonist, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolating it. The compound itself is required. See Fiers v.Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen v.Baird, 30 Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 148 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. Therefore, only the isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2, but not the breadth of the claims meet the written description provision of 35 U.S.C. § 112, first paragraph.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating cachexia, does not reasonably provide enablement for preventing a pathological feeding behavior, cachexia by administering any receptor antagonist. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to which the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally,

the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The Nature of Invention: The claimed invention is drawn to a method of preventing a pathological feeding behavior, cachexia in an animal comprising administering an effective amount of a mammalian melanocortin 4 (MC-4) receptor antagonist to the animal.

The state of the prior art and the predictability or lack thereof in the art: Cachexia is defined as loss of weight and muscle mass caused by disease. Cachexia is a wasting syndrome that causes weakness and a loss of weight, fat, and muscle. Patients with advanced cancer; AIDS and some other major chronic progressive diseases may appear cachectic. Cachexia can occur in people who are eating enough, but who cannot absorb the nutrients. However, cachexia is not the same as starvation. A healthy person's body can adjust to starvation by

slowing down its use of nutrients, but in cachectic patients, the body does not make this adjustment. Bednarek , Maria (US Patent No. 6,693,165) teach a number of antagonist compound that specifically bind to MC-4 receptor for the treatment of eating disorder related to underweight, cachexia or anorexia or bulimia of any cause in humans (column 4, lines 35-38). However, the term "prevention" is interpreted as to stop this symptom or disorder from any future occurrences. The specification does not guide on use of any MC-4 receptor antagonist such as a chemical compound or peptides. The specification does not enable any method of prevention of cachexia in mammals by administering any receptor antagonist.

The amount of direction or guidance present and the presence or absence of working examples: Given the teachings of unpredictability found in the art, detailed teachings are required to be present in the disclosure in order to enable the skilled artisan to practice the invention commensurate in scope with the claims. These teachings are absent. While there are some teachings in the specification on pages 33-39 showing administration of aguti related protein (AGRP) could resist weight loss but this still does not prevent from future occurrences. The specification does not provide any example of administering a receptor antagonist to prevent cachexia.

The breadth of the claims and the quantity of experimentation needed: Because the claims encompass administering an antagonist of MC-4R to prevent a pathological feeding behavior, cachexia in an animal, in the light of the teachings of the unpredictability found in the art discussed and because of

the supra lack of sufficient teachings in applicants disclosure to overcome those teachings, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Cone et al. (US Patent No. 6,100,048).

Claims are drawn to a method of preventing a pathological feeding behavior, cachexia in an animal comprising administering an effective amount of a mammalian melanocortin 4 (MC-4) receptor antagonist to the animal.

Cone et al teach a method of characterizing a MC-4 receptor antagonist as stimulator of feeding behavior in an animal (column 5, lines 40-43). They disclose method steps of treating a pathological eating disorder comprising providing food to an animal not deprived of food at least for 12 hours, with or without administering MC-4 receptor antagonist. They teach that the method can

be used for treating pathological disorder cachexia which occurs in cancer patients (column 12, lines 28-30).

Claims 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Dooley et al. (US Patent No. 6,350,430).

Claims are drawn to a method of preventing a pathological feeding behavior, cachexia in an animal comprising administering an effective amount of a mammalian melanocortin 4 (MC-4) receptor antagonist to the animal.
Dooley et al teach a method of using MC-4 receptor antagonist compounds such as HP467 which antagonizes feeding behavior and weight loss by MC-4R agonist HP 228 in male Sprague-Dawley rats (Example VIII). Dooley et al do not explicitly state this behavior as cachexia. However, cachexia is characterized by body weight loss and loss of apetite. Therefore, Dooley teaches a method of treating cachexia in an animal.

Claims 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Bednarek (US Patent No. 6,693,165).
Claims are drawn to a method of preventing a pathological feeding behavior, cachexia in an animal comprising administering an effective amount of a mammalian melanocortin 4 (MC-4) receptor antagonist to the animal.
Bednarek et al teach many MC-4R specific antagonists such as HS014, HS024 and HS028 and a method of treating eating behavior related to underweight,

cachexia or anorexia or bulimia comprising an effective amount of compound of formula I (column 4, lines 36-48). Thus, Bednarek et al meet all the limitations of instantly claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eileen B. O'Hara

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19 December 2005
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